Centers for Medicare & Medicaid Draft Policy
Monitoring of Erythropoietin for Beneficiaries with End Stage Renal Disease

Background

Recombinant erythropoietin (rEPO), a drug manufactured and distributed by Amgen, is used for anemia management for patients with renal disease. It is FDA-indicated to maintain hematocrit levels within a target range of 30-36 percent.

The current methodology for monitoring EPO claims was implemented with limited scientific analysis. It limits monitoring of EPO to post-payment review based on a 90-day rolling average of claims. The target average hematocrit to trigger action is 37.5 percent, to provide recognition of naturally occurring variability in hematocrit levels. Additionally, higher levels could be maintained upon medical justification by the treating physician. This methodology and its revisions were issued through a series of temporary instructions.

In the fall of 2003, CMS solicited scientific information from the ESRD community in order to develop a permanent evidence-based policy for EPO monitoring. The scientific literature demonstrated that patients with hematocrit levels within the target range had better health outcomes than those with hematocrits below the target level. The data also demonstrated that there is considerable natural variability in individual patient hematocrit levels, making it difficult to consistently maintain a hematocrit within the narrow range of 33-36 percent.

In July 2004 CMS posted a proposed policy for monitoring of EPO in patients with ESRD. The proposed policy suggested that Medicare contractors would conduct medical review on EPO claims for ESRD patients using the following methodology.

- Claims for EPO with hemoglobin levels below 13 (or hematocrit of 39) on a single claim should not be targeted for review.
- Claims with hemoglobin levels between 13.0 and 13.9 (or hematocrit of 39 to 42) should be reviewed if the patient has received a monthly dose of EPO greater than 40,000 IU. If the higher dosage has not been medically justified, contractors should limit payment to the 40,000 IU level.
- Claims with hemoglobin levels 14.0 or greater (or hematocrit equal to or greater than 42) should be reviewed if the patient has received a monthly dose of EPO greater than 20,000 IU. If the higher dosage has not been medically justified, contractors should limit payment to the 20,000 IU level.

CMS accepted formal public comment on the proposed policy until October 7, 2004. Additional public comments were presented and considered, including a consensus recommendation by the Kidney Care Partners into early 2005.

Final Policy

After considering all of the comments submitted, CMS developed the following policy which is announced in CR 4135.

Effective April 1, 2006 Medicare will implement a national monitoring policy to promote the efficient use of EPO and/or darbepoietin alfa (Aranesp) in the Medicare ESRD in-facility dialysis population. The Food and Drug Administration labeling for EPO recommends that as the hematocrit approaches a reading of 36 percent, the dose of the drug should be reduced by 25 percent.

In order to allow for unanticipated increases in hematocrit, Medicare contractors will not initiate monitoring until the hematocrit level reaches 39.0 (or hemoglobin of 13.0). For claims with hematocrit readings above the threshold of 39.0 (or hemoglobin above 13.0), the dose should be reduced by 25 percent over the preceding month.

If the dose has been reduced by 25 percent, dialysis facilities report modifier GS on the claim. Modifier GS is defined as "Dosage of EPO or Darbepoetin Alfa has been reduced 25% of preceding month's dosage."

When the GS modifier appears on the claim, Medicare contractors will make payment based on the reported dosage. For claims with hematocrit levels above 39.0 (hemoglobin above 13.0) without modifier GS, Medicare contractors will reduce the dosage payable by 25 percent of that reported on the claim.

Medicare contractors will not make payment for dosage of EPO in excess of 500,000 IUs per month or dosage of Aranesp greater than 1500 mcg per month. If dosage exceeds these thresholds, Medicare contractors will return the claim to the provider as a medically unbelievable error.

These hematocrit requirements apply only to EPO or Aranesp furnished as an ESRD benefit under §1881(b) of the Social Security Act (the Act). EPO or Aranesp furnished incident to a physician's service is not included in this policy. Carriers have discretion for local policy for EPO and Aranesp furnished as "incident to service."